Review of Department of Health's Response to the Quality of Care at Hillside Health Center

A Report to the Governor of Rhode Island

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Executive Summary

The Governor of Rhode Island, Donald L. Carcieri commissioned this internal review in response to concerns about the quality of care received by residents at Hillside Health Center (Hillside) and the Department of Health's (DOH) regulatory oversight and response. The primary purpose of the review is to:

1. Review how DOH addressed quality of care concerns at Hillside as they relate to the care received by Resident #1; and
2. Provide recommendations to the Governor on how DOH's oversight of licensed healthcare facilities can improve the quality of care Rhode Islanders receive in nursing homes.

In conducting our review, we interviewed DOH staff including the Director, Patricia A. Nolan, MD, MPH and Raymond Rusin, Chief of Facilities Regulation who oversees the survey and certification process of nursing homes. Interviews were also conducted with the primary decision maker for Resident #1, Ombudsman staff, and health care professionals involved in the care of Resident #1. In addition, we reviewed copies of the medical record for Resident #1, as well as surveyor notes and findings from their inspections.

The organization and quality of information collected and provided by Facilities Regulation at DOH made an assessment of DOH's response to Resident #1 and to Hillside difficult. Surveyors obtained facility and residents information through observational methods and from the records maintained by Hillside. The information gathered by DOH did not trend progress of individual residents being monitored nor did it consistently include information on the size of pressure ulcers to adequately assess if their response to Resident #1's condition and to other residents could have been more aggressive. In addition, the medical record of Resident #1 maintained by Hillside, inclusive of physician and nurses' notes, was also poorly organized and contained conflictive and inconsistently recorded information. The medical record was not a straightforward tool for the Hillside health care team and attending physician to fully assess the progression of Resident #1's pressure ulcers. Despite a complicated medical record, it did contain sufficient information for the attending physician and nurse practitioner caring for Resident #1 to question the adequacy of the treatment prescribed and if, and how well, their orders were followed.

The staff from Facilities Regulation visited Hillside a total of 71 times from November 4, 2003 (the time of annual inspection) through June 6, 2004 (closure of Hillside). Twenty of the visits were conducted while Resident #1 was a resident at Hillside. For eleven of these visits surveyors noted problems with the care provided to Resident #1. Four of such visits resulted in Hillside being cited for deficiencies, one ordered the transfer of Resident #1 to another facility, and the final visit monitored the transfer process. There were 11 different surveyors involved in conducting inspections at Hillside. In addition to monitoring visits by DOH, Resident #1 was seen at Hillside 17 times by the attending physician or the nurse practitioner working for him from November 21, 2003 through February 25, 2004.

DOH's response to the care received by Resident #1 focused primarily on seeking compliance with nursing home regulations rather than on actions aimed at either ensuring adequate care delivery for problems identified for Resident #1 or for improving the quality of care at Hillside. When the decline in Resident #1's pressure ulcers was discovered on February 2, 2004, DOH should have taken more aggressive action to prevent further deterioration. By then, Resident #1 had been found on two separate occasions to have worsening pressure ulcers and to be receiving poor care. Furthermore, by February 13, 2004 when DOH cited Hillside for "Immediate Jeopardy," there was ample evidence that Hillside was unable to treat and prevent further deterioration of pressure ulcers for Resident #1 and other residents at Hillside. On this day, DOH took the first action to prevent further decline in Resident #1's condition by ordering the move of Resident #1 to a unit within the facility with more stable staff. On February 28, 2004 the surveyors again found significant problems with the pressure ulcer care and Facilities Regulation ordered that the resident be transferred to another facility immediately.

Hillside had been inspected on a near annual basis since it's opening in 1999. For the past three years DOH issued deficiencies related to poor pressure ulcer care. This was one of the principle areas of concern to the surveyors during their monitoring visits from January 2004 through Hillside's closure in June 2004. The Facilities Regulation staff at DOH described Hillside as a "yo-yo" facility because upon every revisit following an annual survey they found Hillside to be compliant with regulations. Thus, the facility seemed to go up and down like a "yo-yo". Surveyors identified the same pattern during their monitoring visits. At some visits they discovered problems and at others the care appeared adequate. The conclusion of a yo-yo pattern not requiring more aggressive interventions appears to reflect an event by event analysis by Facilities Regulation rather than a pattern/trend analysis of the bigger picture of problems at a facility.

Most of DOH's actions and timeline of inspections appear to be based on or dictated by Federal procedures related to inspecting nursing homes. However, DOH did take some actions faster than outlined by the Federal process. The Director of DOH stopped new admissions to Hillside on December 31, 2003, two weeks after DOH's revisit that found continued non-compliance. The Federal Regional Office recommended stopping new admissions on February 4, 2004. Given the concerns DOH had with Hillside, Hillside's past performance on surveys, DOH should not have waited two weeks, from the December 19 inspection until December 31, to stop all admissions. Similarly, DOH should have started more frequent monitoring earlier than January 2004, two months after the annual survey that identified numerous deficiencies, several of those for the third consecutive time.

During our interviews with staff in Facilities Regulation, it became apparent that the Federal process for inspecting nursing homes currently dominates the inspection process in Rhode Island, since it funds most of their activities. It dictates the frequency of visits, the actions to be taken and, most importantly, standards of practice. Federal guidelines prohibit surveyors from providing any technical assistance or advice to nursing homes

following an inspection. Thus, the surveyors' approach in the case of Hillside and Resident #1 is consistent with a regulatory compliance structure that relies on penalties to enforce regulations. While important, penalties may have the unintended effect of worsening the facility's ability to provide quality care and do not lead to changes that will improve resident care. Over reliance on the Federal nursing home inspection process, which has been repeatedly criticized nationally, significantly contributed to the manner in which DOH addressed concerns at Hillside both before and after the November 2003 inspection. This is an issue in other states as well.

We also identified several other issues related to DOH's authority over licensed health care facilities that require improvement. These include the notification process of residents/families of deficiencies, the complaint investigation process, the inspection process overall, and the limited resources available at DOH to conduct inspections.

Nursing home regulations require DOH to notify the nursing home administrator of all their survey findings but do not expressly require notification of residents, families, resident council, medical director or owner. DOH relies upon the administrator to notify residents, their primary decision maker, medical director, staff and attending physicians of problems identified by the surveyors. DOH should have notified the family and attending physician of their concerns with Resident #1, even though it is not explicitly stated as Federal protocol or state regulation to do so. It is unclear what role the Ombudsman program plays or should play in these situations.

The attending physician is only notified if a deficiency meets Federal criteria for "substandard care." The criteria for substandard care are defined at too high a level resulting in few physicians being notified about quality of care concerns. In addition, the notification does not specify the resident nor the problem identified other than listing the citation code and name.

Resident #1's attending physician and nurse practitioner were occasionally present at Hillside on the same day as the surveyors. However, the medical staff did not approach the Facilities Regulation to inquire about the nature of their visits or to follow up on the "substandard of care" letter received to determine if the letter related to one of their patient(s). Similarly, it does not appear that the attending physician and nurse practitioner asked questions about the quality of care delivered or compliance with their orders for Resident #1 based on the decline in Resident #1's pressure ulcer.

The complaint investigation process at DOH is not functioning effectively. Since Hillside's opening in 1999, DOH had conducted three on-site complaint investigations at Hillside (i.e., August, 2001, July, 2002 and August, 2002). No on-site complaint investigations were conducted between the annual inspections of October 2002 and November 2003. Thirteen complaints were received during that time period. DOH currently reviews complaints at the time they are filed and only immediately investigate "serious complaints" that resulted in "harm" as defined by Federal guidelines. All other complaints are filed and investigated at the time of the annual inspection. The process for

giving feedback to individuals filing complaints and the parties involved or affected by the complaint is inadequate and in need of improvement.

Many nursing homes provide excellent quality of care. Even in poor performing facilities, such as Hillside, some residents receive good care. A strategy of enforcement and inspections which does acknowledge that some providers provide better care than others and thus does not target poor performing facilities appears to be ineffective, especially with limited resources. Information on complaints, staffing levels, and staffing turnover as well as information suggestive of financial solvency problems pointed to problems at Hillside before the November 2003 annual inspection. Taken altogether, these indications of instability could have led to more frequent and focused inspections, which may have avoided the closure of Hillside and Resident #1's outcome.

During our interview with the surveyors they identified the lack of resources as a reason for less aggressive complaint investigations. Limited resources is also cited for precluding Facilities Regulation from conducting more targeted surveys of poor performing facilities. They also identified a need for consultants with specific clinical expertise such as dietary and physical therapy backgrounds to assist them in conducting surveys. Lastly, they identified inadequate computer resources. While most of their work is performed "in-the-field" at the nursing home, they do not have laptop computers and must share computers at DOH. This decreases their efficiency and effectiveness in monitoring and trending information. They also have been unable to conduct internal quality assurance and improvement activities due to the current workload and priorities given available staffing and resources.

The story of Resident #1 and the ultimate closure of Hillside Health Center point to systematic failures – owner, administrators, physicians, nurses, certified nurse assistants - that did not support the adequate care of residents. Licensed health care facilities are accountable for the care they deliver. Health care professionals practicing at health care facilities are accountable for the quality of care delivered to patients and responsible for informing patients (and decision makers) of when a facility is not meeting standards of care.

In the case of Hillside, surveyors invested large amounts of time monitoring the facility. Regulators have a role to ensure compliance with regulations, but they also have an equal obligation to ensure patient safety. If this role is not consistent with current regulatory practice based on Federal regulation, then it should be clearly articulated and acknowledged in State regulation or statute.

As illustrated in this review, many of the problems identified resulted from issues in enforcing existing statutes and regulations, implementation failures or impaired processes coupled with inadequate resources. Quick changes to existing legislation or regulations may not lead to meaningful and sustained improvements. Based on the internal review and issues identified both with Resident #1's care and DOH's oversight of Hillside, we recommend to the Governor the following actions:

1. Improve Resident, Family and attending physician notification of deficiencies in care cited by DOH
2. Improve the Complaint investigation process.
3. Improve Internal policies and procedures at DOH
4. Increase Inspection Resources
5. Create a State Appointed Safety Monitor/Improvement program.
6. Monitor financial solvency of nursing homes
7. Require and enforce “owner” accountability
8. Strengthen the procedure for licensure of new DOH care facilities.

1. PURPOSE

The Governor of Rhode Island, Donald L. Carcieri, commissioned this internal review in response to concerns about the quality of care received by residents at Hillside Health Center (Hillside) and the Department of Health's (DOH) response to those concerns. This review focuses on the care delivered to Resident #1 that led to Resident #1 being transferred to another nursing home and DOH's regulatory oversight and actions taken in response to problems identified with Resident #1 and at Hillside overall. The primary purpose of the review is to:

1. Review how DOH addressed quality of care concerns at Hillside as they relate to the care received by Resident #1; and
2. Provide recommendations to the Governor on how DOH's oversight of licensed healthcare facilities can improve the quality of care Rhode Islanders receive in nursing homes.

2. REVIEW PROCESS

In conducting our review, we interviewed Department of Health staff including the Director, Patricia A. Nolan, MD, MPH, Raymond Rusin, Chief of Facilities Regulation[1] and Administrators of boards of licensure. We also interviewed the primary decision maker for Resident #1, staff from the Ombudsman program and health care professionals involved with Resident #1. In addition, we reviewed copies of the medical record for Resident #1 as well as surveyor notes and findings from their inspections at Hillside. Several organizations associated with the nursing home industry were asked for comments and suggestions about the survey and certification process of nursing homes. For a complete list of individuals interviewed, material reviewed and organizations contacted see Appendix A.

The organization and quality of information collected and provided by Facilities Regulation at DOH made an assessment of DOH's response to Resident #1 and to Hillside difficult. The information from DOH did not trend progress of individual residents being monitored nor did it consistently collect information on the size of pressure ulcers to adequately assess if their response to Resident #1's condition and to other residents could have been more aggressive. In addition, the medical record of Resident #1 maintained by Hillside, inclusive of physician and nurses' notes, was also poorly organized and contained conflictive and inconsistently recorded information. The medical record was not designed as a straightforward tool for the Hillside health care team and attending physician to fully assess the progression of Resident #1's pressure ulcers. Despite a complicated medical record, it did contain sufficient information for the attending physician and nurse practitioner caring for Resident #1 to question the adequacy of the treatment prescribed and if, and how well, the physician's orders were followed.

[1] The Office of Facilities Regulation is housed within the Division of Health Services Regulation at the Department of Health. Facilities Regulation has responsibilities for the licensing of health care and assisted living facilities.

3. FINDINGS OF RESIDENT #1 REVIEW

a. "Resident #1" History.

Resident #1[2] was relatively healthy when admitted to Hillside in April 2000 except for several stable but chronic medical problems. Resident #1 did well over the next two years until late 2002, when Resident #1 suffered a fractured left hip. Following surgery, Resident #1 suffered from a wound infection with resistant bacteria. This resulted in Resident #1 declining in cognitive function, mobility and nutritional status all of which raised the risk of developing a pressure ulcer (i.e., bed sore). Resident #1 was admitted to the hospital in June 2003 for chronic infection of her hip replacement, requiring surgery to remove the infected replacement. This resulted in further limiting her mobility, further increasing her risk for pressure ulcers. Resident #1 developed a Stage I pressure ulcer[3] on the left buttock in August 2003, which was still present at the time of the November 2003 annual survey. For a complete detailed listing of surveyor findings and actions taken by DOH see Appendix B. Pressure ulcers are quite common among nursing home residents in Rhode Island and nationwide. However, in the large majority of cases, pressure ulcers can be successfully treated in nursing home facilities, particularly for Stage I and II ulcers. The inability of Hillside to prevent and successfully treat pressure ulcers among their residents is at the core of the problems.

Resident #1 was seen by surveyors at nearly every visit but one for a total of 20 times during this time period (Appendix B). In addition, Resident #1 was seen 17 times by Resident #1's attending physician or the nurse practitioner working for him (see appendix I). Hillside's administrators, nurses and medical director, attending physician and Facilities Regulation did not notify the family of Resident #1 about the surveyors' findings of poor quality of care. Nor was the family notified of the Facilities Regulation's recommendations to move the resident within the facility or transfer to another facility. The surveyors notified the nursing staff of their findings at each exit interview and the administrator either in person or in writing. This notification process is current protocol and within the parameters of federal and state regulations.

Resident #1's care related to pressure ulcers was often inadequate by Hillside. As a result, the left buttock pressure ulcers did not improve and significantly worsened after the diagnosis of pneumonia on January 24, 2004. The ulcer(s) were found increasing in size and depth at nearly each visit that month. While there was minimal improvement in

[2] Resident #1 is used throughout this document; however, Facilities Regulations assigns new resident number for each survey event. Thus, Resident #1 on publicly available documents is not the same person. References to Resident #1 in this document, however, refer to the same individual.

[3] Pressure ulcers are classified by depth of skin damage ranging from Stage I to Stage IV
Stage I = persistent redness and bogginess without a break in the skin
Stage II = break in skin but not through the outer skin layer (e.g. similar to abrasion or rug burn)
Stage III = damage extends through outer layer into the underlying skin tissue but not deeper
Stage IV = damage extends into deep underlying tissue such as muscle or bone.

one or two of the ulcers, the overall trend was of continued decline. When the ulcer was discovered to be a Stage IV on February 13, 2004 DOH cited immediate jeopardy and moved Resident #1 to a unit within the facility with more stable staff. They also initiated daily monitoring visits which included an unexpected visit at 3:30 AM. No significant problems with Resident #1 pressure ulcer care were noted from February 14-19, 2004.

By February 20, 2004 surveyors began to encounter episodes of improper pressure ulcer care. The surveyors recommended a wound care consult on 02/23, which occurred on 02/25. On February 28, 2004, based on the significant decline in Resident #1 condition and care, DOH ordered that the resident be transferred to another facility, which occurred on the following day. Documentation of the daily monitoring visits during the 7 days prior to Resident #1's move described several isolated and different episodes of questionable care. While none of these episodes by themselves represent serious problems, taken in total and in the context of the previous problems with Resident #1's care and decline in ulcer condition, DOH should have acted sooner to remove Resident #1 from the facility.

b. Issues identified during Resident #1's review

Resident #1's medical care at Hillside related to the prevention and treatment of pressure ulcers did not meet all of the recommended standards outlined in the medical literature and Federal guidelines (see appendix H). The development and progression of the pressure ulcers are rarely due to the actions or inaction of any one individual or isolated episodes of non-adherence to standards of practice. Pressure ulcers develop due to failures in the systems and organizational culture that do not ensure reliable and consistent delivery of care. Despite having appropriate policies for the management of pressure ulcers, Hillside's administrators, physicians, and nurses did not ensure that these processes were performed consistently over time to prevent and treat pressure ulcers. For example,

a. Internal efforts to track pressure ulcers and take corrective actions were not consistent and often contained missing information necessary to make appropriate clinical decisions.
b. Internal processes to monitor the delivery of care (e.g. dressing changes, repositioning, nutritional, and incontinence care) were not done consistently.
c. Staff was unaware of the need for dressing changes; could not perform dressing changes as ordered by the physician; and often used improper technique when performing dressing changes.
d. Pain associated with dressing changes was neither assessed nor treated.

Resident #1's care was a marker for the overall failure of systems at Hillside to adequately prevent and treat pressure ulcers. There were days when the care appeared to be done correctly and other days when it was not. Similarly, the failures in delivering consistent care was not confined to one aspect of pressure ulcer care but related to repositioning, pressure relief, dressing changes, wound assessments, and incontinence care. Taken in isolation any one episode may not be a problem. However, taken

altogether these episodes, coupled with the evidence of a growing number of pressure ulcers at Hillside and worsening of existing pressure ulcers among the residents, indicate that Hillside had a system wide failure in the delivery of pressure ulcer care. This is further supported by the repeated deficiencies for pressure ulcer care that Hillside has received over the past three years.

It appears that Facilities Regulation analyzed the data for Resident #1 on an event-by-event basis, rather than in total and in context of findings at Hillside for other residents. This event-by-event approach fosters the conclusion that some facilities operate like a "yo-yo"; good one day and bad another or that resident care is good one day and bad another. However, licensed health care facilities should deliver consistent and reliable care not a yo-yoing sort of care. The current method of collecting data from nursing homes that includes the use of multiple surveyors over time hinders the ability of DOH to evaluate the "bigger picture" of consistent, reliable care.

The frequency of monitoring and speed in which DOH acted was quicker than outlined by Federal guidelines. However, DOH's major response to the deficiencies found at Hillside was to give citations, increase the frequency of visits, levy and increase fines, deny admissions, and threaten closure. This punitive approach does not address underlying problems at the facility and does not allow for the immediate attention to residents who have developed complications from poor care (e.g. pressure ulcers). Levying fines or denying admissions to institutions with poor financial solvency may only exacerbate the problem by further limiting resources needed to attend to residents' requirements. However, DOH's response was consistent with Federal surveying guidelines and with a prevailing regulatory compliance standard of practice. Advice and recommendations on improving care is not a function of the inspection process.[4] Complimentary and distinct strategies that can assist poor performing facilities and that can help ensure patient safety once deficiencies are identified are needed.

This internal review illustrated the lack of organization and quality of information of the medical records maintained by Hillside as a significant issue. While the organization and quality of information contained in Resident #1's medical record is similar to most nursing homes and hospital records, it raises serious concerns about patient safety and quality of care. The medical record of Resident #1, inclusive of physician and nurses' notes, was poorly organized and contained conflictive and inconsistently recorded information. The medical record was not a straightforward tool for the Hillside health care team and attending physician to fully assess the progression of Resident #1's pressure ulcers. Despite a complicated medical record, it did contain sufficient information for the attending physician and nurse practitioner to question the adequacy of the treatment prescribed and if, and how well, the physician's orders were followed. The development of electronic medical records and utilization of other health information technologies can help overcome these problems.

[4] Federal guidance currently prohibits surveyors to provide recommendations when conducting Federal surveys. However, Federal regulations do not appear to prohibit directed guidance nor do state regulations appear to prohibit surveyors from providing recommendations to Facilities with poor performance.

4. DOH's oversight of Hillside and issues identified

a. Oversight prior to November 2003

DOH's initial licensure of Hillside Health Center took much longer than typically due to concerns about the capacity of the applicant to adequately meet the licensing requirements. Due diligence by the Health Services Council over several years did not reveal any grounds by which to deny licensure to this facility. Subsequent to issuing licensure it was identified that corporate entities associated with Hillside's ownership were involved with other nursing facilities that had significant quality of care or fiscal problems. Current statutes and regulations need to be reviewed to determine what modification are required to allow an applicant's past performance in and out of the health care sector to be used when making licensure determinations.

Despite initial concerns and subsequent track record, DOH's oversight and monitoring of Hillside consisted of annual survey visits and three complaint investigations in 2002 (see appendix C). Hillside had been inspected on nearly 12-month intervals since it's opening in 1999. Although annual surveys are "unannounced", they are not "unexpected." The last three annual surveys at Hillside all occurred in either October or November. In anticipation of their annual survey, Hillside had conducted a "mock survey" three weeks before the State's annual survey on November 4, 2003. In addition, most of the annual surveys are conducted during the normal workweek and normal business hours. Currently, surveyors conduct approximately 11-12% of survey inspections on weekends or off hours, which exceeds federal guidelines of 9%. The survey schedule is primarily dictated by the Federal process since they fund a majority of the survey and certification process. State funds do not adequately fund additional survey activity.

A trend in the type of deficiencies received by Hillside is evident when the findings from the last three years are examined (see appendix D). At each survey, Hillside received a deficiency for poor food service, and for the past three years deficiencies related to poor pressure ulcer care. These were the areas of most concern to the surveyors during their monitoring visits from January 2004 through closure. At the December 2003 revisit, Hillside was found to still be non-compliant in the areas of pressure ulcer care and food service. In response DOH denied all new admissions on December 31, 2003. The timing of this action exceeded the Federal guidelines but was too slow given the past record at Hillside.

The poor financial situation at Hillside significantly contributed to its inferior quality of care and ultimate closure. Financial issues played a role in staff turnover and lack of supplies, which in turn contributed to the poor quality of care. The financial solvency of licensed health care facilities is not monitored by DOH and other Departments within the Office of Health and Human Services. Financial solvency is not used as a trigger to conduct more frequent and focused inspections or actions to prevent deterioration in quality of care. At Hillside, the Ombudsman learned about financial problems prior to government agencies from staff whose paychecks bounced. The Ombudsman program reported to Facilities Regulation in August 2002 that staff and vendors were reporting

bounced checks. Legislation that provides the Office of Health and Human Services authority to monitor financial solvency of licensed DOH care facilities is needed.

Personnel issues related to staffing levels, staff training and turnover, and use of agency (temporary) staff may also have contributed to the poor quality of care delivered to Resident #1 and other residents in the facility. Changes in staffing levels and turnover and leadership turnover often are early indicators of potential quality of care issues. Hillside had staffing levels that were significantly below the state and national average. In addition, they experience increased turnover, which required the use of agency staff to cover unfilled positions. The responsibility for ensuring adequate staffing levels and staff training lies with the owners and leadership of the facility. DOH should require submission of staffing information and use this information to trigger focused inspections.

b. Oversight from November 2003 to closure

The staff from Facility Regulation visited Hillside a total of 71 times from November 4, 2003 through June 6, 2004 (Appendix E summarizes the chronology of these visits). There were a total of two annual visit, five revisits and sixty-four monitoring visits. It is clear that surveyors spent a great deal of time and energy in the evaluation of Hillside's compliance with regulations.

Many other residents at Hillside also developed pressure ulcers and some appeared to receive poor care similar to Resident #1. However, the quality and organization of the information provided by Facilities Regulation and Hillside makes this determination difficult. For example, at each annual survey and revisit, the residents are assigned a new "resident number." In Resident #1's case there was different "resident numbers" at each of the four full surveys conducted from November 4, 2003 through March 3, 2004. This makes trending outcomes for individual residents difficult between inspections. In addition, during the monitoring visits there was no summary document used to track trends in care or outcomes overtime by resident nor was enough information collected (such as size of pressure ulcer) to make such a determination. The follow-up on previous findings appeared to be better when the surveyor remained constant.

A review of the weekly monitoring visits from January 2004 showed that at nearly each visit additional residents acquired pressure ulcers and some others already with pressure ulcers were worsening. While the surveyors refer to residents by name during their monitoring visits, the use of different surveyors and lack of trending of care by resident hinders seeing the "big picture" for individual residents and for the facility as a whole. Thus, it is unclear if other residents should have been removed from Hillside along with Resident #1. Examining the trends and looking at the "big picture" may have resulted in a different response to Hillside's quality of care issues. Based on Hillsides past performance and the data from the November 2003 annual survey and December 2003 revisit DOH should have moved more quickly to close admissions, to increase inspections, and based on the continued non-compliance, to close the facility.

As per regulations, DOH notified Hillside's Administrator of all of their findings. The Administrator is then responsible to share the findings with the residents, primary decision makers for the residents, resident council, owner, medical director and staff. Hillside did not communicate with the primary decision maker for Resident #1 or the attending physician about the deteriorating condition of Resident #1's pressure ulcers. DOH should have notified Resident #1's primary decision maker of their concerns with Resident #1, although it is not explicitly stated to do so in Federal protocol or state regulation. DOH should initiate a process through which inform residents and/or resident's primary decision makers upon findings of immediate jeopardy or problems with the quality of care being provided to individual residents. In addition, regulations related to facility/resident/primary decision maker communications need to be clarified and enforced.

DOH only notifies the attending physician when one of their patients has been included in a deficiency citation that is rated as "substandard care." However, Facilities Regulation uses the Federal guidelines to define substandard care (i.e., deficiencies with a severity level of F or H or higher -see appendix F for the severity rating scheme and "substandard care" definition). This criterion results in too few notifications to attending physicians and does not promote efforts to ensure appropriate care for affected individuals. While, Facilities Regulation staff sent a letter to the attending physician on January 7, 2004, the letter only indicated that the facility overall had been cited for substandard care related to "F314-Quality of Care (483.25)" but did not specify the resident(s) resulting in this citation nor what a F314 citation addresses. Nonetheless, Resident #1's attending physician and nurse practitioner did not contact Facilities Regulation to inquire about the nature of their visits or to follow up on the "substandard of care" letter received about poor quality of care at Hillside. While, the medical record indicates periodic communication between the attending physician and family member, it is unclear if the communication related to the deteriorating condition of Resident #1. We recommend increased communication about quality of care concerns between DOH and the residents, their primary decision makers and attending physician for residents involved in quality of care citations rated at lower levels than those defined by the Federal survey process.

c. Issues related to the survey process identified during the internal review

The surveyors' responsibilities do not include the provision of advice or technical assistance to nursing homes. This is consistent with federal regulations and guidance regarding the role of surveyors that prohibits surveyors from providing any technical assistance or advice. Their responsibility is to identify areas of non-compliance with regulations. The facilities' responsibility is to correct the problems. The standard of practice for surveyors is extremely rigid. Assistance in the form of directed action plans, requiring specific clinical consultation for care problems (e.g. wound care experts or referral to wound clinics) would be warranted. It is unclear if current statutes and regulations allow DOH to force changes in facility leadership, external management or

consultation. These are necessary strategies for DOH to employ in their efforts to prevent closure of poor performing facilities in the future.

The verification of a facility's plan of correction (POC) in response to deficiencies found during an inspection involves a revisit by DOH to the facility to examine compliance with regulations. The surveyors do not focus on evaluating if changes were made related to the deficiencies cited or if the POC was implemented. Rather, they focus on checking for compliance with the regulations. The revisits are often conducted by different surveyors. This approach coupled with different surveyors may contribute to the perception of "yo-yo" facilities.

Presently, the medical director, director of nursing, resident council or other health care professionals in a facility are not required to participate in the development and submission of the POC to DOH. Only the administrator is notified of the deficiencies and is responsible for submitting the POC. While most facilities involve individuals other than the administrator during the development and implementation of the POC, the poorer performing facilities such as Hillside often do not. In addition, regulations require facilities to provide space and support for resident/family councils, but they do not require that such councils exist nor be involved in the development or approval of the POC. Regulations should be modified to require the resident/family council and the medical director to approve a POC.

Process for Investigation of Complaints

The complaint investigation process in the Office of Facilities Regulation is not functioning effectively. Facilities Regulation conducted three complaint investigations at Hillside since it's opening (August 2001, July 2002 and August 2002), but none between the annual inspections of October 2002 and November 2003. Thirteen complaints were received during that time period. The current protocol is to review complaints at the time they are filed, and only immediately investigate "serious complaints" that resulted in "harm" as defined in the Federal guidelines. A majority of the complaints are filed by nursing homes themselves and already include a plan of correction associated with the complaint. All other complaints are filed and investigated at the time of the annual inspection. In addition, the complaints are not trended or maintained in any type of database that can allow the identification of trends requiring action before the annual inspection.

There is no complaint investigation team available. Many complaints are also received and transmitted to Facilities Regulation by the Ombudsman program. While efforts are underway to clarify the working relationship between DOH and Ombudsman program, further clarification of the role of each entity needs to be refined. Both parties are supposed to notify each other about annual surveys as well as complaints. However, this is not happening consistently.

Delaying complaint investigation until the annual survey has three potentially adverse consequences. First, complaints cannot be adequately investigated because of changes in staffing and residents. Information necessary to the investigation may no longer be

available at the time of the annual survey. Secondly, if problems are identified, implementation of corrective actions may have been delayed, potentially affecting additional residents. Thirdly, the burden of adding complaint investigation to the annual survey team diverts attention away from inspecting compliance with regulations. Many "complaints" are filed by the facilities themselves. However, what constitutes a complaint and a reportable event needs to be reviewed and revised.

Presently, the process for responding to individuals filling complaints does not include feedback to the all of the parties involved in the complaint situation. DOH's formal response/decision is sent to the complainant only. Facility incident reports may result in a citation if substantiated. The process of providing feedback needs to be expanded and should also address the delay in feedback that may occur if most complaints continue to be investigated at the annual survey

Resources are one of the main reasons cited for the current ineffectiveness of the complaint investigation process. Lack of resources was cited in relation to both human-power needs (e.g., a. survey team whose primary responsibility is to investigate complaints) as well as equipment (e.g., computers and software to track complaints). The Federal government provides a majority of the resources that support DOH's survey and certification process. Actions taken by the survey team in excess of the Federal requirements must be covered by State funds. Current Federal funds only cover immediate investigation of the most severe complaints. All other complaints are investigated at the time of the annual survey or the next on-site inspection.

Boards of Professional Licensure

Communication between Facilities Regulation and licensure boards is slow and ineffective. In the case of Hillside, while the nursing home administrator was reported to the Board of Nursing Home Administrators[5], these reports were not filed until February 16 and March 17, 2004. Similarly, reports to the Board of Nurse Registration and Nursing Education for the Director of Nursing were also delayed. Complaints against the physicians involved with Resident #1 were not filed with the Board of Medical Licensure and Discipline until August 31, 2004. While forwarding reports to the licensure boards does not imply professional misconduct, licensure boards require timely, complete and accurate information to investigate adherence to professional standards. In addition, the licensure boards need to examine the responsibility that health care professionals have to be aware of and to advocate for their patients when licensed health care facilities are providing poor quality of care to their patients. Historically, this has not been a reason for referral to the boards of licensure.

During our interview with the surveyors they identified a lack of available consultants with specific clinical experience, such as dietary and physical therapy expertise, to aid in the survey process. They also identified the absence of a team to investigate complaints and staff available to provide technical assistance to nursing homes. Consistent with Federal guidelines they asserted that their role should not involve assistance or advice to health care facilities and any such assistance needs a "firewall" between the regulatory

[5] Hillside Nursing Home Administrator's license was revoked.

process and technical assistance process. They also felt that it was not the role of government to assist nursing homes (i.e., private business) improve their delivery of care other than through inspections to determine adherence with regulations. Surveyor's findings should in turn be used by facilities to implement corrective actions.

Surveyors mentioned inadequate computer resources. While most of their work is performed "in-the-field" at the nursing home, they do not have portable computers. They must return to DOH and enter information into computers, which are often shared by more than one individual. They currently have one large workspace for all the surveyors to sit with an average of one computer for every two surveyors. The lack of a laptop computer for surveyors results in the inefficient use of their time. Transcribing notes from the field delays the provision of more timely feedback to facilities. We also observed that the information collected in the field by hand is difficult to interpret both due to illegibility, lack of organization and incompleteness. Use of laptops and software available for completing inspections could significantly improve the efficiency and effectiveness of the survey process.

The lack of staff resources also impacts DOH's ability to addresses crises such as occurred with Hillside. The resources required to address issues at Hillside put them over a month behind schedule inspecting other licensed health care facilities. This lack of resources has also limited Facilities Regulation from conducting quality assurance and improvement activities on their procedures.

5. Nursing Home Stakeholder Comments

Five Stakeholder organizations representing the nursing home industry and physicians providing care to elderly (see appendix A) made comments and suggestions about how to improve the survey process. All cautioned against rushing to implement more legislation or adding new regulations in response to what they perceived as mismanagement of the nursing home. They all pointed out that many nursing homes, owners, and administrators are performing very well. Many also identified the survey process as "inherently antagonistic." Several expressed concern that the surveyors focus on minutia at the expense of the residents. They also would like to see the reliability between surveyors and teams improved. The use of different surveyors with different background (e.g. dietary vs. nursing) appears to affect the focus of some inspections. The philosophy of the Office of Facilities Regulation of "no assistance or advice" is unhelpful to the industry's efforts to make improvements in response to deficiencies. They support the concept of having Facilities Regulation or DOH provide more assistance and advice. They also requested regular interactions (such as educational seminars) to clarify confusion about regulations and discuss concerns that the Facilities Regulation have about nursing home quality as well as to hear DOH's suggestions on how to improve. Many also supported the idea of targeting surveys. Rather than expending resources to try and survey everyone on the same schedule with the same intensity, they recommended using available information and past performance to target inspections to identify the poor performers who give the nursing home industry a bad name.

6. CONCLUSIONS

The story of Resident #1 and the ultimate closure of Hillside Health Center point to systematic failures – owner, administrators, physicians, nurses, certified nurse assistants - that did not support the adequate care of residents. Licensed health care facilities are accountable for the care they deliver. Health care professionals practicing at health care facilities are accountable for the quality of care delivered to patients and responsible for informing patients (and decision makers) of when a facility is not meeting standards of care.

In the case of Hillside, surveyors invested large amounts of time monitoring the facility. Regulators have a role to ensure compliance with regulations, but they also have an equal obligation to ensure patient safety. If this role is not consistent with current regulatory practice based on Federal regulation, then it should be clearly articulated and acknowledged in State regulation or statute. Without meaningful changes, similar outcomes are likely to occur in the future.

The system failed both in the delivery of care by health care providers and in the monitoring and enforcement of quality of care standards. This failure occurred in part because the resident/patient does not appear to be at the center of the system. Instead, the health care providers, nursing homes and regulators and the process of delivering care or enforcing the delivery of care appears to be at the center. In addition, while many of the individuals involved in this case devoted extraordinary amounts of time and effort, the current system and resources available prevented faster and more effective action. The organization of information may have also prevented faster and more focused action by DOH. Nonetheless, review of the information available suggests that DOH should have acted faster in the case of Resident #1 and more aggressively and quicker with Hillside.

The Federal process currently dominates the inspection process in Rhode Island. The over reliance on the Federal nursing home inspection process, which has been repeatedly criticized nationally, significantly contributed to the manner in which DOH addressed concerns at Hillside. The influence of the Federal survey process on Facilities Regulation procedures and standards of practice impeded their ability to provide more aggressive oversight of Hillside prior to the November 2003 inspection.

The Director of DOH stopped new admissions within two weeks of the revisit that verified no improvement and well before the Federal timeline. Although DOH took aggressive actions faster than outlined by the Federal process, these actions should have been performed sooner based on the available evidence of poor quality of care at Hillside. In addition, when the significant decline in Resident #1's pressure ulcer was discovered, DOH immediately moved Resident #1 to a higher level of care within the facility and initiated daily monitoring visits including a surprise visit at 3:30 AM. When they found problems again on January 28th they ordered that the resident be transferred immediately to another facility, which occurred the following day.

Reliance on penalties alone does not yield the level of improvement and speed of improvement necessary when problems with quality of care are identified. In fact, when poor quality is related to financial solvency issues, penalties may actually make the situation worse by further restricting funds and resources to fix the problem. A complimentary process of enforcement and technical assistance is likely to yield better results. For example, the prevalence of pressure ulcers in nursing homes has remained unchanged over the past ten years despite an emphasis by Facilities Regulation to cite facilities for poor pressure ulcer care. Inadequate pressure ulcer care remains as one of the top clinical related deficiencies received by nursing homes nationally and in Rhode Island. Evidence suggests that most pressure ulcers can be prevented or healed when the organization develops a system to ensure implementation of key steps recommended in the medical literature. While we do not expect regulators to provide technical assistance to licensed health care facilities, they have a legitimate responsibility to ensure patient safety. Similarly, we believe that the state also has a responsibility to direct health care facilities and providers to improve health care delivery. Because of Facilities Regulation's standard of practice of evaluating for regulatory compliance, we recommend that quality improvement activities and oversight be placed outside of the regulatory evaluation process.

Many nursing homes provide excellent quality of care. Even in poor performing facilities such as Hillside, some residents receive good care. A strategy of enforcement and inspections which is predictable in frequency and intensity and which does not target poor performers appears to be inefficient and ineffective as well. DOH should develop plans to use their limited resources better by targeting poorer performing facilities. This will require changes in legislation since current legislation requires equal number of inspections regardless of past performance or available evidence suggesting instability or poor quality of care.

The governing individual, body or entity of a licensed health care facility is accountable for the quality of care delivered. This is particularly important when owners make financial decisions that adversely affect the facility's ability to deliver quality care to patients. Current State regulations require facilities to disclose persons with an ownership or controlling interest (see appendix G). However, it is unclear as to the accountability they have for poor quality of care as a result of their actions. Legislation and regulations need to be improved to hold individual owners of licensed health care facilities more accountable.

When the information collected by DOH from inspections of Hillside is trended, patterns of poor care before and after the November 2003 annual survey suggest that more aggressive actions should have been taken by DOH. For example, the facility had been repeatedly cited for poor pressure ulcer care and DOH had received numerous complaints to this effect. Also, surveyors did not start weekly visits until January 2004 (two months after the November 2003 survey that resulted in the fourth citation for pressure ulcer care and food service deficiencies). Surveyor notes also described increasing numbers of pressure ulcers at Hillside during each weekly visit in January 2004. Likewise, surveyors' daily monitoring in March and April showed new residents developing ulcers, old

pressure ulcers worsening, and episodes of poor care related to pressure ulcer management. However, the notes do not contain enough information to make a thorough evaluation or to draw firm conclusions about these apparent patterns or continued quality problems. Surveyors obtained facility and residents information from the records maintained by Hillside and through observation of staff care delivery and the residents. The variation in information collected by different surveyors conducting the visits limited our ability to analyze trends and patterns of care. Better organization of the medical record including the development of electronic medical records and utilization of other health information technologies can help overcome these problems.

7. RECOMMENDATIONS

As evident in this review, many of the problems identified resulted from a narrow interpretation of existing legislation or regulations, implementation failures or poor processes. Quick changes to existing legislation or regulations may not lead to meaningful and sustained improvements that will avoid future quality of care problems.

Based on the internal review and issues identified both with Resident #1's care and DOH's oversight of Hillside, we support the Governor's preliminary recommendations made last week and add some additional recommendations.

1. **Resident, Family and attending physician notification.** DOH should immediately begin reporting results of deficiency citations related to individual patient care to the patient (or primary decision maker) as well as attending physician. The criteria for reporting should be lowered from the current criterion of "substandard care" as defined by Federal guidelines (see appendix F) to any DOH related deficiency in care. This will allow patients and their providers to make their own judgments, and if necessary, take action to prevent care from deteriorating further. Notification should be specific and described in language understandable to the patient, primary decision maker and physician. This should apply to all licensed health care facilities in Rhode Island and in accordance with privacy laws and regulations about confidentiality of health care information.

2. **Improve the Complaint investigation process.** Complaints need to be investigated more quickly and feedback must be provided to the patient, healthcare professionals involved and complainant. This also must be done in compliance with current privacy laws and regulations about confidentiality of health care information but may be able to be implemented without changes in current legislation or regulations. We also recommend that the Office of Health and Human Services review all of the complaint investigation programs supported by the Departments of Children, Youth and Families, Elderly Affairs, Health, Human Services and Mental Health, Retardation and Hospitals, including complaints to professional licensure boards, for timeliness and feedback of results to individuals involved in the complaint.

3. **Create State Appointed Safety Improvement program at DOH.** Licensed health care facilities that exhibit poor quality of care may require assistance and advice to make improvements including consultation, technical and management assistance related to improving organizational policies and procedures, personnel, and internal monitoring of quality. A safety monitoring program with authority to take actions that result in changes that will improve patient safety and care should be established at DOH. DOH needs the authority to appoint a monitor to oversee the operations of a deficient facility without petitioning for receivership.

4. **Improve policies & procedures at DOH.** The Office of Facilities Regulation needs to make changes to the survey process. These changes should include the following:
    a. Develop a plan to target facilities that includes using data on financial solvency, staffing levels, use of agency staff, complaints, and past survey performance. This will require introducing legislation to change current state requirements for the same number of visits to all nursing homes.
    b. Develop a plan to improve the survey process including:
        i. consistent assignment of surveyor during revisits and monitoring visits
        ii. system to track and monitor same residents over time, especially during monitoring visits
        iii. conducting more unexpected and off hour inspections of licensed health care facilities
        iv. more effective communication with professional licensure boards
        v. periodic "training seminars" with nursing homes on common problems being found and clarifying interpretation of existing regulations.
    c. Strengthen regulations about the role of the medical director of nursing homes that address the following:
        i. Involvement in the development and approval of plan of corrections
        ii. Involvement in the hiring of new administrators and directors of nursing.
        iii. Attendance at annual inspection and follow-up visits to assess compliance with deficiencies.
        iv. Inclusion on all communications regarding the inspection process sent to the administrator
    d. Modify regulations to require resident/family councils in licensed long term care facilities such as nursing homes and assisted living facilities and their involvement in the plan of corrections.
    e. Improve coordination with the Ombudsman program**.** Clarify the roles of the two programs. Request a plan outlining the roles and responsibilities between the Ombudsman program and Facilities Regulation
    f. Improve the collection and publicly report data on quality of care of licensed DOH care facilities. Current legislation allows DOH to direct providers to collect and publicly report quality of care information.

However, the scope of quality information currently reported is limited. In addition, the presentation and dissemination of this information does not allow consumers to use the information to make meaningful decisions about their care.

5. **Increase Inspection Resources**. The survey and certification process will require additional state resources to
    a. support additional staff to complete complaint investigations
    b. hire consultants to assist with focused clinical expertise.
    c. update and increase technology to improve DOH's ability to manage complaints about care.

6. **Monitor financial solvency of nursing homes** and all licensed health care facilities. We recommend at least annual monitoring of the financial solvency of licensed facilities. We also recommend that DOH use financial solvency and complaints suggesting problems with financial solvency as an indicator to trigger inspections to evaluate any impact that this may have on patient care. Legislation and regulations will be necessary to provide authority to the Office of Health and Human Services to monitor financial condition of health care facilities.

7. **Require and enforce "owner" accountability** for nursing homes (and all other licensed health care facilities). Current State regulations require disclosure of "owner" of nursing homes. These regulations should be reviewed in detail to ensure that individuals can not hide behind legal barriers such as limited partnerships and limited liability corporations to hide ownership and responsibility for financial and management decisions that adversely affect the care received by Rhode Islanders. The penalties available to hold "owners" accountable for the quality of care delivered in their facilities should also be reviewed and strengthened. Department Directors with authority to enforce existing accountability statutes should submit a plan outlining a process to better enforce existing and any new penalties. This recommendation may or may not require new legislation to increase the accountability of individuals who own interests in licensed health care facilities such as nursing homes.
8. **Strengthen procedure for licensure of new DOH care facilities**. Introduce legislation that prohibits individuals who have been involved in ownership of failed health care facilities due to poor quality of care or other businesses due to mismanagement from being involved in future health care facilities. Utilize concerns raised during licensure determination in decisions regarding more frequent and targeted inspections and oversight.

Appendix A. Outline of Internal Review Process

In evaluating the Quality of Care delivered to Resident #1 and DOH's response, the following documents were reviewed:

1. Resident's #1 medical record from Hillside and from the facility where Resident #1 was transferred on February 29, 2004. Permission to view the medical record was obtained from Resident #1's family.
2. Documents and internal notes from Department of Health's Office of Facilities Regulation related to their inspections of Hillside nursing home
3. Data on Hillside's past performance including deficiency reports, quality indicators and quality measures.
4. State and Federal Nursing Home Regulation focusing on those related to pressure ulcers and disclosure of ownership.
5. Department of Health's policies and procedures on the management of state and federal surveys of nursing homes.

In addition to reviewing documents, the following individuals were contacted for interviews about the care at Hillside and DOH's response:

1. Department of Health staff
    a. Patricia A. Nolan, MD, MPH, Director of Health
    b. Office of Facilities Regulation
        i. Chief, Office of Facilities Regulation - Raymond Rusin
        ii. Surveyor Supervisor - Lori Rounds
        iii. State Survey Inspectors (six)
    c. Office of Health Professional Regulation
        i. Administrator, Board of Medical Licensure and Discipline - Robert Crausman
        ii. Administrator, Board of Nurse Registration and Nursing Education - Jean Marie Rocha
2. Health care providers at Hillside Health Center
    a. Medical Director of Hillside
    b. Attending physician and nurse practitioner for Resident #1
3. Primary decision maker for Resident #1
4. Ombudsman program Director and staff

Lastly, we invited comments and suggestions from nursing home stakeholder organizations including:

a. Rhode Island Chapter of American Health Care Association
b. Rhode Island Chapter of American Association of the Homes & Services for the Aging
c. Rhode Island Chapter of American College of Health Care Administrators
d. Rhode Island Chapter of American Medical Directors Association
e. Rhode Island Chapter of the American Geriatrics Society

Appendix B. Summary of Inspections Related to Resident #1, 11/03 - 03/04

Date Completed	SURVEY Type	Resident #1 Reviewed	Surveyor Notes about Resident #1	DOH Actions Related to Resident #1
11/4/2003	Annual	yes	Pressure ulcers: One open Stage II on left buttock "center 1 cm" and brief soaked with urine. No dressing placed 1 hour after shower. Did not receive medications that were ordered by physician on two occasions.	Cited for deficiencies • F-314 – poor pressure ulcer care; • F-426 missed medication ordered by physician. Required Plan of Correction. Levied daily fines.
12/19/2003	Revisit	yes	Pressure ulcer: Stage II Coccyx ulcer 2 cm x ½ cm (newly found by surveyor) Left buttock 2cm x 2cm. Observed on December 16 and 17 2003 both ulcers without dressings (staff stated out of dressing supplies for at least 3 days); also found unchanged in brief with urine and stool without dressing in place; Despite order for pressure relief of heels and pillow under legs- observed neither being done. Records from December and November show no dressing change recorded 2 and 15 times, respectively. Order for thickening liquids to prevent aspiration in chart but observed resident to be served thin liquids twice.	Cited for deficiencies • F-282 failed to provide services as ordered; • F-312 failure to provide care related to personal hygiene; • F-314 poor pressure ulcer care; • F-367 failure to serve diet ordered by physician; and • M-085 failure to assess for pain Stopped new admissions and readmissions. Letter sent to attending physician on January 7, 2004. Required plan of correction by January 14, 2004. Continued fines.
1/9/04	Monitor	yes	Care plan reviewed and current	No new deficiencies.
1/12/04	Monitor	yes	No comments on Resident #1	None.
1/20/2004	Monitor	yes	Two stage II pressure ulcers: one coccyx and left buttock. "Resident lying in bed in a brief without a dressing on stage II pressure ulcer."	"No new deficiencies identified"
2/2/2004	Revisit	yes	Stage III pressure ulcer on left buttock and a stage II on coccyx; resident complained of pain during dressing change but not given pain medications. Resident found lying in urine and stool. No dressings on wounds noted twice, staff failed to change dressing per physician orders. No repositioning while in chair from 9:30AM to 1:00PM. Inadequate support surface on bed.	1. Cited for • F-314 poor pressure ulcer care; • F-309 failure to adequately manage pain. Required plan of corrections by February 20, 2004. Continued fines.

Date Completed	SURVEY Type	Resider #1 Reviewe	Surveyor Notes about Resident #1	DOH Actions Related to Resident #1
2/13/2004	Monitor	yes	Stage II on her coccyx and stage IV 9 by 5cm and 3cm deep on her left buttock, she was found lying in bed without a dressing in place. Staff used incorrect technique in dressing the ulcer.	1. Cited deficiency for • F-314 poor pressure ulcer care 2. Immediate Jeopardy. 3. Resident transferred from the 3rd to the 4th floor. 4. Increased daily fine
2/14/2004	Monitor	Yes	Dressing in place and resident on pressure relief mattress.	No new deficiencies
2/15/2004	Monitor	Yes	Pressure ulcer dressed appropriately.	No new deficiencies
2/18/2004	Monitor	No	N/A	N/A
2/19/2004	Revisit	Yes	Observed at 3:30 AM with dressing intact, properly positioned on gel mattress, bed clean and dry,	1. Remove Immediate Jeopardy 2. No new deficiencies
2/20/2004	Monitor	Yes	Seated properly in chair on gel cushion. Dressing change not done properly: barrier cream not used.	No new deficiencies
2/21/2004	Monitor	Yes	Stage IV. "Staff advised she is non-compliant."	No new deficiencies
2/22/2004	Monitor	Yes	Dressing in place but resident found in stool. Incomplete documentation of fluid intake and urine output.	No new deficiencies
2/23/2004	Monitor	Yes	Stage IV left buttocks "needs a wound consult."	No new deficiencies
2/24/2004	Monitor	Yes	Stage IV "needs a wound consult", however, seen by nurse practitioner. Urine appears concentrated and staff not recording intake and output of fluids.	No new deficiencies
2/25/2004	Monitor	Yes	Dressing in place but different dressing used than ordered because dressing ordered by physician not currently available. Seen by a wound care nurse. Care plan stated fluid intake goal 1200 cc per day but intake on 830cc today.	No new deficiencies
2/26/2004	Monitor	Yes	Nurse contaminated gel before putting in ulcer stopped by surveyor. Fluid intake of 1020cc less than goal of 1200cc per day.	No new deficiencies.
2/27/2004	Monitor	Yes	Wound dressing change using proper technique. Wound bed appears to have necrotic tissue. Fluid intake of 780cc less than stated goal of 1200cc.	No new deficiencies
2/28/2004	Monitor	Yes	Resident found incontinent of stool with dressing saturated with	1. Ordered transfer of resident to another facility – administrator

Date Completed	SURVEY Type	Resider #1 Reviewe	Surveyor Notes about Resident #1	DOH Actions Related to Resident #1
			stool. Staff had not checked her dressing because "I only work here every other weekend, I didn't know she had a dressing." Dressing change done incorrectly and staff not aware of how to use wound care products correctly. Also, nurse had not received report about resident from prior shift. Lastly, resident noted to have fallen out of bed earlier in evening and no changes made to prevent future falls.	and nursing notified of action. 2. No new deficiencies
2/29/2004	Monitor	yes	Resident noted to have trouble breathing during evening requiring oxygen and was complaining of "not feeling well" to surveyor. Despite daughter informing staff that vicodin causes resident to have nausea – vicodin given to resident for pain.	1. Transferred to another facility 2. No new deficiencies.

Appendix C. Chronology of DOH Surveys at Hillside, 05/99 - 06/04

Survey Process Key			
Type of Survey			
(I) Initial	(R) Recertification/Annual License	(F) Revisit	(C) Complaint – Abbreviated survey

Hillside Nursing Home - Chronological survey history:

Survey Exit Date	Type of Survey	Severity/Scope Report	Enforcement Recommended	Enforcement Imposed
5/17/99	**Initial**	n/a	n/a	n/a
1/19/00	**Annual (R)**	Addendum B (8 deficiencies)	Directed Plan of Correction	
3/21/00	Revisit (F)	Corrected	n/a	n/a
12/01/00	**Annual (R)**	Addendum C	CMP[6] - $800 per day (G).	Opportunity to correct.
1/30/01	Revisit (F)	Corrected	n/a	n/a
8/8/01	Complaint (C)	Addendum D	CMP - $2,000 per day (Double G).	CMP - $2,000 per day NoC[7].
9/12/01	Revisit (F)	Corrected	n/a	" "
11/8/01	**Annual (R)**	Addendum E (6 Deficiencies)	Denial of payment DoPNA[8].	Opportunity to correct.
12/10/01	Revisit (F)	Corrected	n/a	n/a
7/3/02	Complaint (C)	Addendum F	Directed plan of correction.	Opportunity to correct.
8/1/02	Revisit (F)	Corrected	n/a	n/a
8/15/02	Complaint (C)	Addendum G	Directed plan of correction.	Opportunity to correct.
Survey Exit Date	***Type of Survey***	***Severity/Scope Report***	**Enforcement Recommended**	**Enforcement Imposed**
9/13/02	Revisit (F)	Corrected	n/a	n/a
10/28/02	**Annual (R)**	Addendum H (13 Deficiencies)	CMP – $800 per day (G).	Opportunity to correct.
1/16/03	Revisit (F)	Corrected	n/a	n/a
11/4/03	**Annual (R)**	Addendum I (24 Deficiencies)	CMP - $1,000 per day (Double G).	CMP - $250 per day; NOC.
12/19/03	Revisit 1st (F)	Addendum I2	Sub-standard quality of care; State ordered (12/31/04) denial of new admissions.	CMP running.

[6] Civil money penalty
[7] No opportunity to correct
[8] Denial of payment for new admissions

			State monitoring begins 01/04.	
2/2/04	Revisit 2nd (F)	Addendum I3	Continued non-compliance.	CMP running.
2/13/04	State monitoring	Addendum I4	Immediate Jeopardy; CMP.	CMP - $5,000 per day.
2/19/04	Revisit (F-IJ	IJ Corrected	n/a	CMP $250 per day running; Denial of Medicare admissions.
3/3/04	Revisit 3rd (F)	Addendum I5	Continued non-compliance	CMP $250 running.
Receiver named 3-4-04				
4/16/04	Revisit 4th (F)	Addendum I6	Continued non-compliance	Termination track; CMP running.
5/13/04	**Annual (R-State)**	Addendum J	Continued non-compliance State report issued for licensure	Termination; CMP total: $76,000.

Note: Addendums available at DOH

Appendix D. Trend in Type and Severity of Deficiencies for Hillside

	Citation Severity[9]				
Deficiency Type	**01/00**	**04/01**	**11/01**	**10/02**	**11/03**
F-371 Store/prepare/distribute food under sanitary conditions	C	F	F	F	F
F-314 Proper treatment to prevent/heal pressure sores		G	D	D	G
F-282 Services by qualified persons in accordance with care plan	D		D	D	D
F-241 Dignity	D	E			D
F-328 Proper treatment/care for special care needs		D	D		E
F-159 Facility management of resident funds				C	C
F-280 Development/preparation/review of comprehensive care plan			D		D
F-324 Supervision/devices to prevent accidents				D	D
F-309 Provide necessary care for highest practical well being		D		D	
F-278 Accuracy of assessments/coordination with professionals	D			D	
F-312 ADL care provided for dependent residents	D			D	
F-164 Personal privacy/confidentiality of records				D	
F-272 Comprehensive assessments				E	
F-325 Resident maintain nutritional status unless unavoidable				G	
F-428 Resident drug regimen reviewed monthly by pharmacist				D	
F-514 Clinical records meet professional standards				D	
F-167 Survey results readily accessible to residents	C				
F-252 Safe/clean/comfortable/homelike environment			D		
F-274 Assessment after a significant change	D				
F-318 Range of motion treatment and services	D				
F-520 Facility maintains quality assurance committee		C			
F-253 Environment maintain sanitary/orderly/comfortable interior					C
F-156 Notice of rights and services					C
F-156 Notice of rights and services about Ombudsman program					C
F-279 Comprehensive care plan					D
F-281 Meet standards of implementing physician orders					D
F-313 Treatment and receive assistive devices for vision/hearing					D
F-323 Environment free of accident hazards					E
F-364 Food nutritional value/flavor and served at proper temperature					F
F-365 Food prepared to meet individual needs					D
F-367 Diets prescribed by attending physician					D
F-372 Dispose of garbage and refuse properly					C
F-426 Pharmacy services assure administering medications					D
F-469 Pest and rodent control					C
M-275 Organizational management handling resident funds					X
M-320 Medical records discharge summaries completed					X
M-710 Administration of medication by non-licensed personnel					X
M-755 Dietary services by full-time qualified individual					X
M-805 Dietary manual approved and available					X
M-810 Three meals served daily without 14 hour interval					X
M1300 Water supply/temperature/pressure					X
K-027 Life safety code standard – door smoke barriers and self-closing					X
K-050 Fire drills held					X
TOTAL #	8	7	6	13	30

[9] Citations preceded with F severity ranges from A to L. See Appendix F for Federal citation severity rating system.
A to C = No actual harm with potential for minimal harm
D to F = No actual harm with potential for more than minimal harm that is NOT immediate jeopardy
G to I = Actual harm that is not immediate jeopardy
J to L = Immediate Jeopardy to resident health or safety
No severity rating for other citations preceded with M or K

Appendix E. Summary of Surveys and Surveyors conducting visits at Hillside from 11/03 through 06/04

		Surveyor Conducting Visit										
Date Completed	Survey Type	A	B	C	D	E	F	G	H	I	J	K
11/4/2003	Annual			X	X	X	X		X			
12/19/2003	Revisit											
1/9/2004	Monitoring				X							
1/12/2004	Monitoring								X			
1/20/2004	Monitoring			X								
2/2/2004	Revisit											
2/13/2004	Monitoring											
2/14/2004	Monitoring			X								
2/15/2004	Monitoring					X						
2/18/2004	Monitoring				X							
2/19/2004	Revisit											
2/20/2004	Monitoring		X								X	
2/21/2004	Monitoring						X					
2/22/2004	Monitoring										X	
2/23/2004	Monitoring					X						
2/24/2004	Monitoring					X					X	
2/25/2004	Monitoring					X					X	
2/26/2004	Monitoring										X	
2/27/2004	Monitoring					X					X	
2/28/2004	Monitoring			X								
2/29/2004	Monitoring				X							
3/3/2004	Revisit											
3/4/2004	Monitoring						X					
3/6/2004	Monitoring			X								
3/8/2004	Monitoring			X								
3/9/2004	Monitoring			X								
3/10/2004	Monitoring			X								
3/11/2004	Monitoring			X								
3/12/2004	Monitoring			X								
3/14/2004	Monitoring				X							
3/15/2004	Monitoring			X								
3/16/2004	Monitoring					X						
3/17/2004	Monitoring					X						
3/18/2004	Monitoring					X						
3/19/2004	Monitoring					X						
3/20/2004	Monitoring						X					
3/22/2004	Monitoring						X					
3/25/2004	Monitoring			X								
3/26/2004	Monitoring			X								
3/27/2004	Monitoring			X								
3/28/2004	Monitoring										X	
3/29/2004	Monitoring			X								
3/30/2004	Monitoring					X						
3/31/2004	Monitoring								X			
4/1/2004	Monitoring										X	
4/2/2004	Monitoring				X							

Date Completed	Survey Type	Surveyor Conducting Visit										
		A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**
4/3/2004	Monitoring			X								
4/4/2004	Monitoring					X						
4/5/2004	Monitoring						X					
4/7/2004	Monitoring						X					
4/9/2004	Monitoring										X	
4/12/2004	Monitoring											X
4/14/2004	Monitoring						X					
4/16/2004	Revisit											
4/17/2004	Monitoring			X								
4/19/2004	Monitoring						X					
4/20/2004	Monitoring										X	
4/22/2004	Monitoring					X						
4/25/2004	Monitoring						X					
4/28/2004	Monitoring	X										
4/29/2004	Monitoring							X				
4/30/2004	Monitoring									X		
5/2/2004	Monitoring					X						
5/4/2004	Monitoring								X			
5/7/2004	Monitoring						X					
5/8/2004	Monitoring									X		
5/13/2004	Annual											
5/23/2004	Monitoring										X	
5/28/2004	Monitoring										X	
6/2/2004	Monitoring					X						
6/11/2004	Monitoring						X					
TOTAL												
Annual	**2**											
Revisit	**5**											
Monitoring	**64**	**1**	**1**	**17**	**5**	**15**	**12**	**1**	**5**	**2**	**12**	**1**
All Surveys	71											

Appendix F. Scope & Severity of Deficiency Citations

Scope & Severity
The federal government's enforcement process requires the State Survey Agency to assign scope and severity levels for deficiencies. After these have been determined, they are given a later designation. The level of the deficiency is determined by scope (how widespread the problem is), and severity (how much potential or actual harm it has caused to residents.

Severity			
Immediate jeopardy to resident health or safety	**J**	**K**	**L**
Actual harm that is not immediate jeopardy	**G**	**H**	**I**
No actual harm, potential for more than minimal harm	**D**	**E**	**F**
No actual harm, potential for minimal harm	**A**	**B**	**C**
	Isolated	Pattern	Widespread
	Scope		

Substandard Care
Deficiencies cited at F, H, I, J, K, or L are considered substandard care and are grounds for civil monetary penalties, non-payment or decertification if not corrected.

Scope:

Assesses how widespread the deficiency is in the nursing home. Using the three levels of scope:

1. An isolated problem: one or a very limited number of residents are affected
2. A pattern of problems: more than a limited number of residents are affected or when the same problem has occurred in several locations in the facility and/or the same number of residents have been affected by repeated occurrence of the deficient practice
3. Widespread scope: the problems causing the deficiencies are found throughout the facility and/or there are systemic failures in the nursing home that have affected or have the potential to affect a large proportion of the residents

Severity:

Assesses how much harm may occur or has occurred to residents as a result of the deficiency. Using the four levels of severity:

1. No actual harm, but has potential for minimal harm.
2. No actual harm, but potential for more than minimal harm.

   A level 2 Deficiency could result in minimal physical, mental or psychosocial discomfort or has the ability to compromise the resident's ability to maintain or achieve highest possible function.
3. Actual harm that is not immediate jeopardy, in other words, life-threatening.

   A level 3 deficiency means a resident has been negatively impacted and his/her ability to maintain or reach the highest functional level has been compromised.
4. Immediate jeopardy to resident health and safety

   A level 4 deficiency requires immediate corrective action because serious injury, harm, impairment or death has been caused, or could be caused, to residents.

   Deficiencies are cited at the highest severity level. If a deficient practice has minimal impact on most affected residents, but has a severe impact on only one of the residents, that deficiency will be cited at the highest severity level observed.

Appendix G. Federal Regulations about Disclosure of Ownership

F522 - §483.75(p) Disclosure of Ownership

(1) The facility must comply with the disclosure requirements of §§420.206 and 455.104 of this chapter.

(2) The facility must provide written notice to the State agency responsible for licensing the facility at the time of change, if a change occurs in--

(i) Persons with an ownership or control interest, as defined in §§420.201 and 455.101 of this chapter;

(ii) The officers, directors, agents, or managing employees;

(iii) The corporation, association, or other company responsible for the management of the facility; or

(iv) The facility's administrator or director of nursing.

(3) The notice specified in the paragraph (p) (2) of this section must include the identity of each new individual or company.

Appendix H. Federal Regulations F-314 Pressure Sores

F314 - §483.25(c) Pressure Sores

Based on the comprehensive Assessment of a resident, the facility must ensure that--

(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and

Intent §483.25(c)

The intent of this regulation is that the resident does not develop a pressure sore while in the facility. If the resident is admitted with or develops a pressure sore, he or she receives care and treatment to heal and prevent further development of pressure sores.

For additional information on prevention, staging and treatment, refer to the staging system found in the booklet "Pressure Ulcers in Adults: Prevention and Treatment, Public Health Service Agency for Health Care Policy and Research."

Interpretive Guidelines §483.25(c)

This corresponds to MDS, section N; MDS 2.0 section I, M, and P when specified for use by the State.

"Pressure sore" means ischemic ulceration and/or necrosis of tissues overlying a bony prominence that has been subjected to pressure, friction or shear. The staging system presented below is **one method** of describing the extent of tissue damage in the pressure sore. Pressure sores cannot be adequately staged when covered with eschar or necrotic tissue. Staging should be done after the eschar has sloughed off or the wound has been debrided. Vascular ulcers due to Peripheral Vascular Disease (PVD) have to be considered separately. They usually occur on the lower legs and feet and are very persistent even with aggressive treatment.

Stage I: A persistent area of skin redness (without a break in the skin) that is nonblanchable. Redness can be expected to be present for one-half to three-fourths as long as the pressure applied that has occluded blood flow to the areas. For example: If a resident is laying on his right side for 30 minutes and turned to his back, redness may be noticed over his right hip bone. Redness in that area can be expected to remain for up to 20 minutes. The survey team then would check to see if the area is nonblanchable. Just having the redness does not indicate a stage I. To identify the presence of stage I pressure ulcers in residents with darkly pigmented skin, look for changes such as changes in skin color (grayish hue), temperature, swelling, and tenderness or texture.

Stage II: A partial thickness loss of skin layers either dermis or epidermis that presents clinically as an abrasion, blister, or shallow crater.

Stage III: A full thickness of skin is lost, exposing the subcutaneous tissues - presents as a deep crater with or without undermining adjacent tissue.

Stage IV: A full thickness of skin and subcutaneous tissue is lost, exposing muscle and/or bone.

Procedures §483.25(c)

Identify if resident triggers RAPs for urinary incontinence, nutritional status, cognitive loss/dementia, psychotropic drug use, and physical restraints. Consider whether the RAPs were used to assess causal factors for decline, potential for decline or lack of improvement.

If **the resident is moribund** (i.e., the resident is terminally ill; semi-comatose or comatose) and life -sustaining measures have been withdrawn or discouraged as documented in the record, pressure sores may be clinically difficult to prevent.

A determination that development of a pressure sore was unavoidable may be made only if routine preventive and daily care was provided. Routine preventive care means turning and proper positioning, application of pressure reduction or relief devices, providing good skin care (i.e., keeping the skin clean, instituting measures to reduce excessive moisture), providing clean and dry bed linens, and maintaining adequate nutrition and hydration as possible

Clinical conditions that are the **primary risk factors** for developing pressure sores include, but are not limited to, resident immobility and:

1. The resident has two or more of the following diagnoses:
    a. Continuous urinary incontinence or chronic voiding dysfunction;
    b. Severe peripheral vascular disease;
    c. Diabetes;
    d. Severe chronic pulmonary obstructive disease;
    e. Severe peripheral vascular disease;
    f. Chronic bowel incontinence;
    g. Continuous urinary incontinence or chronic voiding dysfunction;
    h. Paraplegia;
    i. Quadriplegia;
    j. Sepsis;
    k. Terminal cancer;
    l. Chronic or end stage renal, liver, and/or heart disease;
    m. Disease or drug-related immunosuppression; or
    n. Full body cast.

2. The resident receives two or more of the following treatments:
    a. Steroid therapy;

b. Radiation therapy;
c. Chemotherapy;
d. Renal dialysis; or
e. Head of bed elevated the majority of the day due to medical necessity.

3. Malnutrition/dehydration, whether secondary to poor appetite or another disease process, places resident at risk for poor healing, and may be indicated by the following lab values:
    a. Serum albumin below 3.4 g/dl
    b. Weight loss of more than 10% during last month
    c. Serum transferrin level below 180 mg per dl
    d. Hgb less than 12 mg per dl.

Use these values in conjunction with an evaluation of the resident's clinical condition.

4. If laboratory data are not available, clinical signs and symptoms of malnutrition/dehydration may be:
    a. Pale skin;
    b. Red, swollen lips;
    c. Swollen and/or dry tongue with scarlet or magenta hue;
    d. Poor skin turgor;
    e. Cachexia;
    f. Bilateral edema;
    g. Muscle wasting;
    h. Calf tenderness; or
    i. Reduced urinary output.

Probes §483.25(c)(1)

For each sampled resident selected for the comprehensive review, or the focused review at risk of developing pressure sores, determine, as appropriate, if aggressive preventive care is provided?

For sampled residents, who upon initial admission to the facility, did not have a pressure sore and now have one, determine if pressure sore development may have been avoided:

- Did the facility identify the resident as being at risk for pressure sore(s)?

- Did the facility provide aggressive/appropriate preventive measures and care specific to addressing the resident's unique risk factors (e.g., if serum albumin is below 3.4 mg per dl, provide additional protein in daily snacks)?

- Was this preventive care plan implemented consistently?

483.25 (c)(2)

Based on the comprehensive Assessment of a resident, the facility must assure that –

(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

Probes 483.25 (c)(2)

For all sampled residents who have pressure sores at the time of the survey, including those readmitted from the hospital with a pressure sore that developed in the hospital:

- Are measures to assist healing provided per the plan of care (e.g., relieving pressure, moving the resident without causing shearing, instituting topical therapy which creates a favorable environment for healing, and debriding eschar.

- Are measures to prevent further contamination followed (e.g., wash hands before caring for sore? Observe clean or sterile technique, as indicated, when dressing is changed). All wounds are contaminated (soiled/contain organisms). An infected wound is accompanied by local or systemic symptoms. Clean technique is adequate when caring for a non-infected wound.

- Are universal precautions used during all wound care? (See §483.65, Infection Control.)

- Have the care plan objectives been evaluated? If the pressure sore is not healing, getting larger, or signs of additional skin breakdown are evident, have alternative interventions been considered or attempted?

- Has improvement been noted?

Appendix I. Summary of Physician and Nurse Practitioner's Orders

Date	PU orders	Comments
8/1/03	• Solosite wound gel (gel dressing) • Clean wound with NS[10] and apply solosite gel with dressing	• Monthly recert orders • Signed 8/8/03
9/1/03	• Cleanse Coccyx/buttocks with NS; follow by dermagram with 4x4 gauze, no tape QD & PRN[11] • Dermagram to open areas with each diaper cleanse w NS, 4x4 gauze, no tape • Elevate heels off bed pillow under LE's[12] dsg • LLL-wash BID dry then apply dermagram & bulky dsg[13] • Pressure relief w/chair cushion	• Signed by NP 10/27/03 • Monthly recert orders
9/22/03	• Turn side to side – back for meals only	
10/1/03	• Dermagram to open cocycy areas after cleansing with NS after each incontinent episode & prn 4x4 without tape • Turning schedule – Q2 hrs w/a back for meals only –ok in chair x1 meals • Wheelchair cushions per PT[14] (Use eggcrate until obtained)	• order
10/1/03	• Turn side to side-back for meals only • Cleanse Coccyx/buttocks with NS; follow by Dermagram with 4x4, no tape • Dermragram to open areas with each diaper cleanse w NS, 4x4, no tape • Elevate heels off bed pillow under LE's • LLL-wash BID dry then apply dermagram & bulky dsg • Pressure relief w/chair cushion.	• Signed by NP 10/27/03 • Monthly recert orders
10/2/03	• D/C[15] wheelchair cushion per PT • OT[16] evaluation R/T wheelchair positioning	• order
10/3/03	• OT services 3x/wk x 2ks for wheelchair positioning using wedge cushion, gel cushion, & dycem between cushions	• order
11/1/03	• Turn side to side-back for meals only • Elevate heels off bed pillow under LE's DSG • Pressure relief w/chair cushion • Dermagram to open areas with each diaper cleanse w NS, 4x4, no tape • Dermagram to pen coccyx areas after cleaning with NS after ech incontinence episode and PRN 4x4 dsg with tape • Cleanse Coccyx/buttocks with NS; follow by dermagram with 4x4, no tape QD & PRN • LLL-NS was BID dry then apply dermagram & bulky dsg • Turning schedule Q2 hrs w/a back for meals only-ok in chair x1 meal.	• Monthly recert orders • Signed 11/21/04
11/21/03	• d/c turn side to side, back for meals only • Start turning Q2 hrs w/a back for meal only, ok in chair x1 meals	• Order (see 10/1/03 order)

[10] NS = Normal Saline (e.g. salt water)
[11] QD & PRN = every day & as needed
[12] LE = lower extremities (e.g. legs)
[13] dsg = dressing
[14] PT = physical therapy
[15] D/C = discontinue
[16] OT = Occupational Therapy

Appendix J. Disclosure of Potential Conflicts of Interest

David R. Gifford MD, MPH reports the following potential conflicts of interest in participating as a consultant in this internal review. As Chief Medical Officer of Quality Partners of Rhode Island, he is involved in quality improvement efforts in the nursing home setting funded by the Center for Medicare & Medicaid Services (CMS) which includes working with DOH's Office of Facilities Regulation. In addition, he has received funding from DOH to provide technical input into the implementation of the Health Performance Reporting Program. He has also received funding from several nursing home trade associations to assist, develop, and conduct quality improvement programs for nursing homes. He also serves as medical director for a Rhode Island nursing home as well as a management service organization that includes several RI nursing homes and other licensed health care facilities. Lastly, he is a member of the Brown Department of Medicine and an employee of University Medicine Foundation. The University Medicine Foundation is a practice of approximate 150 practicing physicians. The medical director at Hillside Health Center and the physicians and nurse practitioners who provided care to patients at Hillside, including Resident #1 are also employees of the University Medicine Foundation.